K080655

VII **510K SUMMARY** MAY - 9 2008

Device Name: " Chrysalis"

Legally marketed device: These devices accessorize the current approved medical imaging devices, eg Stationary X ray Systems

Device description: Chrysalis is composed of vinyl-coated polyester, ¼ inch polyurethane foam headliner, poly-pro webbing, Buckles: 2" side-release plastic buckles

Intended Use: These devices are intended to accessorize stationary X Ray Systems.

Assessment of Performance Standards: Not Applicable

◊ **Non-Clinical Testing:** Biocompatibility testing and safety evaluations were deemed to be unnecessary due to a lack of patient exposure to the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2008

META Imaging Solutions
% Mr. Robert J. Staab
Official Consultant
Regulatory and Technical Associates, Inc.
30 Neck Road
OLD LYME, CT 06371

Re: K080655
Trade/Device Name: Accessory to Stationary X Ray System (Chrysalis)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: KPR and MQB
Dated: March 3, 2008
Received: March 14, 2008

Dear Mr. Staab:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1796, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Department of Health and Human Services

Indications for Use

510(k) Number (if known): K080655

A. Device Name: Device Name: Accessory to Stationary X Ray System
Proposed trade name: Chrysalis.

Common name: Medical Imaging Accessory

Indications for Use:

The device described here is an accessory to imaging devices previously approved. In general, the intended professional application is described as follows:

Breast displacement for imaging purposes with the intention of decreasing radiation dose to the breasts and/or improving image quality. The Chrysalis device is reusable and used external to hospital garb; it does not touch the patient's body.

Prescription Use __x_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Center for Devices and Radiological Health / CDRH

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080655